Date: November 30, 2001 DSL-BQA-01-048

To: Hospitals HOSP 22
End-Stage Dialysis Centers ESRD 09

From: Jan Eakins, Chief, PRQI
Bureau of Quality Assurance

Via: Susan Schroeder, Director
Bureau of Quality Assurance

ALERT - Dialyzer Recall by Baxter

On October 18, 2001, following the deaths of 53 patients, four in the United States, Baxter voluntarily issued a recall of the following dialyzers:

A15, A18, and A22 Dialyzers (237015, 237018, 23722)
AF150, AF180, AF 220, Dialyzers (238015, 238018, 238022)
All lots of the above product codes

On November 14, 2001 CMS issued a memo outlining the recall of Baxter dialyzers, labeled either Baxter or Althane. Two additional recalls were included in this memo, and they are:
Ax 1500, Ax2200

The FDA has issued a Medalert, ESRD networks have been asked to communicate this information to all dialysis providers, and CMS has asked state departments to communicate to all hospital providers.

The Wisconsin Health and Hospital Association (WHA) sent out an e-mail Alert to their membership on November 21, 2001.

Attached please find the CMS letter, the Baxter recall notice and customer letter, and a copy of the New York Times article. For additional information you may contact :

CMS Judith Kari at jkari@cms.hhs.gov
Baxter Center for One Baxter at 1-800-422-9837 or 847-948-4770
(Monday through Friday 8:00 – 5:00pm CST)
Wisconsin BQA Lydia Reitman at reitmla@dhfs.state.wi.us

Baxter Healthcare Corporation
Route 120 & Wilson Road
Round Lake, Illinois 60073-0490
847.546.6311

Baxter

URGENT PRODUCT RECALL

October 18, 2001

Subject: A15, A18 and A22 Dialyzers (237015, 237018, 237022).

AF150, AF180, AF220 (238015, 238018, 238022) Dialyzers.
All lots of the above product codes.

Dear Hemodialysis Physician:

Baxter is initiating a voluntary recall of the products specified above that are labeled either Althane or Baxter. This action is being taken due to reports of serious adverse events that have resulted in patient deaths. There is no evidence to date to link these incidents to the dialyzers. This action is being initiated solely as a precautionary measure in the interest of patient safety while the investigations continue. Patient safety is our highest priority.

Among other actions under way, Baxter has established an independent panel of recognized experts in nephrology to understand the potential cause(s) of these unfortunate events.

Our records show that you have received these specific product codes. **Please discontinue use of these product codes immediately.** Contact Hospital Order Support at 1-800-284-4060, extension 2684 (between 7:30 am – 5:00 pm CST) for return of product to Baxter for credit. Limited support is available after hours for emergency situations.

If you have distributed these dialyzers to other facilities, please forward this information immediately.

If you have further questions, you may contact the Renal Helpline (between 7:30 am – 4:30 pm CST) at 1-888-736-2543 (Opt. 2). Please complete and return, via fax, the enclosed reply form to confirm the receipt of this information. Your prompt attention to this matter is greatly appreciated.

Sincerely,

Marge Brown
Director Quality Systems
Baxter Healthcare Corporation

XC: Hemodialysis Center Administrator

Baxter Healthcare Corporation
Route 120 & Wilson Road
Round Lake, Illinois 60073-0490
847.546.6311

Baxter

URGENT PRODUCT RECALL

ALTHANE A-15, A-18, A-22, AF150, AF180 and AF220 DIALYZERS
RECALL DATED 10/18/2001
BAXTER PRODUCT CODES 237015, 237018, 237022, 238015, 238018, 238022

Reply Form

Please complete and return this record to the **FAX** number listed below:
(847) 270-5457

Contact Information (please print)

Name: _____ Title: _____

Facility: _____ City: _____

Address: _____ State: _____

Telephone: _____ Zip: _____

QUANTITY OF PRODUCT ON HAND

We have examined our inventory and report the following:

_____ **No units from this (these) product code(s) remain.**

_____ **Units from this (these) product code(s) remain, and their use has been discontinued.**
(Please call Hospital Order Support for product return and credit)

Signature/Date: _____

Baxter International Inc. 847.948.2000
One Baxter Parkway
Deerfield, Illinois 60015-4633

Baxter

November 5, 2001

Dear Baxter Customer,

Baxter is deeply saddened by the recent reports of hemodialysis patient deaths and we extend our sympathy to family members of those patients. Since first learning of a potential problem with our A and AF series dialyzers, we encouraged a thorough investigation by international health authorities and independent medical experts, in addition to conducting our own in-depth analysis.

Given our utmost concern for patient safety, we continued our intensive investigation, even after exhausting all standard internationally recognized safety and toxicity tests. We diligently pursued every potential lead based on the facts available to us and even began pursuing other less obvious courses of investigation in search of what could be the cause of the unexplained deaths.

Over this past weekend, we believe we have uncovered the probable cause and felt a responsibility to make public our findings immediately, even though confirmatory studies remain under way. Our preliminary tests indicate that a fluid used in the manufacturing of a small number of these dialyzers is the likely cause of the tragic events. Still, we believe there remain substantive gaps in information about the facts associated with many of the patient deaths that will result in ongoing uncertainty. As such and given our overriding priority of patient safety, we've decided the most prudent course of action is to permanently cease manufacturing these dialyzers. We will be working with medical professionals, regulatory bodies, testing authorities, nephrology experts and families of the deceased to address all issues.

It is important that I clarify that our actions only impact the A, AF and AX dialyzers. All other Baxter products remain unaffected by the findings of our investigation and our subsequent decision to cease manufacturing. This includes other Baxter dialyzers, hemodialysis instruments and ancillaries, peritoneal dialysis products and all other Baxter supplied products and services.

Most of you will have been working with your local Baxter representative to determine an alternative dialyzer(s) and we continue to work to ensure continuity of patient care. If you would like to contact Baxter you can either call the Center For One Baxter at 1-800-422-9837 or 847-948-4770 (Monday through Friday, 8:00 a.m. to 5:00 p.m. CST) or click here to obtain contact information for your region.

Baxter International Inc. 847.948.2000
One Baxter Parkway
Deerfield, Illinois 60015-4633

Again, thank you for your ongoing support and confidence in Baxter during our investigations. We are committed to maintaining your confidence, as well as that of your patients, and helping you make the best possible arrangements for your patients. We will continue to keep you informed of any further developments and hope you will contact us with any comments or questions.

Sincerely,

Baxter Finds Possible Link in 53 Deaths

November 6, 2001

By MELODY PETERSEN with EMMA DALY

Baxter International (news/quote) said yesterday that a chemical that it used to manufacture filters for dialysis patients might have played a role in dozens of deaths around the world.

The Food and Drug Administration is investigating the deaths of 53 patients who used the Baxter devices, called dialyzers, which filter toxins out of the blood of patients whose kidneys have failed.

Baxter became aware of possible problems with the filters in August, after several patients died in Spain, but a company investigation had failed to find anything wrong with the devices. The company, which recalled the filters worldwide in mid-October and continued to study them, said it uncovered the probable cause of the deaths over the weekend.

Four of the deaths occurred in the United States, two in Austin, Tex., and two in Kearney, Neb. Federal regulators said yesterday that a doctor at the Nebraska dialysis center was questioning whether the company's filters were to blame.

Twenty-one of the deaths being reviewed by the F.D.A. occurred in Croatia. At least 10 deaths occurred in Spain, 7 in Taiwan, 5 in Germany, 4 in Italy and 2 in Colombia, according to the F.D.A.

The company voluntarily recalled all of its dialyzers in the series A, AF and AX on Oct. 18, sending letters to doctors and asking them to return any unused filters of that type.

Yesterday, Baxter said it had decided to permanently cease manufacturing the dialyzers. They were made by Althin Medical, a company Baxter acquired last year, at a factory in Ronneby, Sweden.

Baxter said it planned to compensate the families of patients who died.

"We are greatly saddened by the patient deaths, and I would like to extend my personal sympathies to family members," Harry M. Jansen Kraemer Jr., Baxter's chairman and chief executive, said in a statement. "We have a responsibility to make public our findings immediately and take swift action, even though confirmatory studies remain under way."

Dr. David W. Feigal, director of the F.D.A.'s center for devices and radiological health, said yesterday that the problem appeared to be that the chemical, a fluid called perfluorohydrocarbon that Baxter uses to manufacture some of the filters, is liquefied at room temperature but becomes a gas if it is warmed to body temperature.

That means the liquid could have created gas bubbles in the bloodstream, Dr. Feigal said.

Regulators are investigating whether the chemical fluid, which Baxter began using in December, is used by other filter manufacturers and whether other patients might have been affected.

"We want to make sure this is not a hidden problem in some other products," Dr. Feigal said.

Baxter, which is based in Deerfield, Ill., said yesterday that it began an internal investigation of the filters after Spain reported that 10 people using its filters had died.

The company said that an early series of tests on the filters had found no problems. Perfluorohydrocarbon is a nontoxic substance, the company said, but it is not labeled for human use.

Sally Benjamin Young, a spokeswoman for Baxter, said the fluid was used in fewer than 10 percent of the filters, those that had been set aside after they failed a quality control test.

The fluid was used to retest the filters, she said.

To cover the cost of recalling the filters and compensating families, Baxter said yesterday that it was setting aside $100 million to $150 million. The cost could exceed the $130 million that Baxter paid for Althin in March 2000.

In Spain, a report by the Ministry of Health that is expected to be released this week will tie the deaths of more than 10 people to Baxter's filters, according to Fernando Garcÿa Lÿpez, an author of the report.

Autopsies on five of those who died found evidence of multiple organ failure "which is not among the usual causes of sudden death" in kidney patients, Mr. Garcÿa Lÿpez said.

Manuel Mata, a lawyer who represents the families of eight people who died in Spain, said his clients were considering filing lawsuits against Baxter in the United States.

Families of people who died after Aug. 18 are especially angry, Mr. Mata said, because hospitals in the city of Valencia continued to use Baxter's dialyzers, despite four deaths in Madrid between Aug. 15 and Aug. 18 and after hospitals in that city stopped using the filters. "There is something very important that must be investigated," Mr. Mata said. "What happened after Aug. 18 when the dialyzers were removed in Madrid for fear they were connected to the deaths?"

"Baxter did not withdraw the dialyzers from Valencia," Mr. Mata said. "They could have pulled the products in that time. Those deaths were avoidable."

Ms. Young, the Baxter spokeswoman, said the company had been told that the deaths in Madrid were not related to the filters. When it learned of the deaths in Valencia, she said, Baxter immediately recalled the filters in Spain and stopped selling them worldwide.

http://www.nytimes.com/2001/11/06/business/06BAXT.html?ex=1006081233&ei=1&en=10d646cbfb2bdd76